PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

JARO, Michael J.
MEDTRONIC VASCULAR, INC.
IP Legal Dept.
3576 Unocal Place
Santa Rosa, CA 95403
ETATS-UNIS D'AMERIQUE

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	20.07.2004
Applicant's or agent's file reference: P1187 PCT	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 03/32441	14.10.2003	22.10.2002

International Patent Classification (IPC) or both national classification and IPC
B05D1/00

Applicant
MEDTRONIC VASCULAR INC.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 22.02.2005

Name and mailing address of the international preliminary examining authority:
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer
Fayos, C

20 Oct. 2004

Formalities officer (incl. extension of time limits)
Ladurner, Y
Telephone No. +49 89 2399-7913

WRITTEN OPINION

International application No. PCT/US 03/32441

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-25 as originally filed

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-23
Inventive step (IS)	Claims	1-25
Industrial applicability (IA)	Claims	-

2. Citations and explanations

see separate sheet

Preliminary note:
All dependent claims relate to "claim 0" and lack therefore clarity (Art. 6 PCT).

The current assessment is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. It the later turns out that is not correct, the document D1 cited in the international search report could become relevant.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1- Reference is made to the following documents:
D1: EP-A-1329230
D2: US-A1-2002051730
D3: US-A1-2002133183
D4: WO-A-9856312
D5: US-A-6096070
D6: WO-A-0243619
D7: WO-A-02074194
D8: WO-A-0187372
D9: EP-A-0701802
D10: US-A-6129705

NOVELTY - Art. 33 (1) and (2) PCT

2- Claims 1-23 lack novelty:

2.1- D2: Drug coated stent useful for the local delivery of drug/drug combinations. The type of coating depends on the type of drug (rapamycin and polymer (outer surface) in combination with heparin (inner surface)). The coating may be uniform or not and continuous or discontinuous.
D2 is novelty destroying for the subject matter of claims 1-23.

2.2- D3: Coated stents. Therapeutic drugs, agents or compounds may be mixed with the biocompatible materials and affixed to at least a portion of the stent (rapamycin and heparin).
D3 is novelty destroying for the subject matter of claims 1-23.

2.3- D4: Coated stents: two or more coating layers of polymeric compositions (inner layer, outer layer). The outer layer may be used as drug delivery system. The inner layer may contain a drug too. The stent can have multiple layers of different polymers with the same or different drugs.
D4 is novelty destroying for the subject matter of claims 6-22.

2.4- D5: Coated stent: two or more layers of different bioactive materials. The same bioactive material will generally not be deposited on the different surfaces of the device within the same layer (i.e. each surface of the device carries different bioactive materials).
D5 is novelty destroying for the subject matter of claims 1-23.

2.5- D6: A portion of an inner surface or an outer surface of a stent is coated with a material containing a polymer and a biologically active material.. Inner and outer portion of the medical device can be coated with different materials. Also, there can be more than one coating on a surface and the entire surface of the stent is not necessarily coated.
D6 is novelty destroying for the subject matter of claims 1-23.

2.6- D7: Medicated stent (S1) with a coating comprising a primer layer (a) comprising a first composition (a1) of at least one polymer, and a drug reservoir layer (b) comprising a second composition (b1) of at least one polymer and active agent(s). One or more drug carrier polymer layers can be applied. Different drugs contained within different layers.

D8: Two coating layers: one with polymer and dexomethasone and the other with rapamycin and polymer.

D9: Stent coated with polymer containing a drug.

D10: Balloon, catheter and coated stent.

INVENTIVE STEP - Art. 33 (1) and (3) PCT

3- No inventive step can be acknowledged for the subject matter of claims 1-23, which lack novelty.

3.1- The features of claims 24-25 are merely some of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

INDUSTRIAL APPLICABILITY - Art. 33 (1) and (4) PCT

4- Claims 1-25 appear to be industrially applicable.

5- Any amendment should be accompanied by a precise indication of the source / support in the originally filed disclosure otherwise the IPER may be drafted on the non amended version only.

PATENT COOPERATION TREATY

Rec'd PCT/PTO 18 APR 2005

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

JARO, Michael J.
MEDTRONIC VASCULAR, INC.
IP Legal Dept.
3576 Unocal Place
Santa Rosa, CA 95403
ETATS-UNIS D'AMERIQUE

RECEIVED
DEC 13 2004
By

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	07.12.2004
Applicant's or agent's file reference: P1187 PCT	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 03/32441	14.10.2003	22.10.2002

Applicant: MEDTRONIC VASCULAR INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer
Nielsen-Hannerup, A
Tel. +49 89 2399-7739

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P1187 PCT		

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 03/32441	14.10.2003	22.10.2002

International Patent Classification (IPC) or both national classification and IPC
B05D1/00

Applicant
MEDTRONIC VASCULAR INC.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19.05.2004	07.12.2004

Name and mailing address of the international preliminary examining authority:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Fayos, C

Telephone No. +49 89 2399-2180

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US 03/32441

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-25 received on 22.07.2004 with letter of 07.07.2004

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	24-25
	No:	Claims	1-23
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-25
Industrial applicability (IA)	Yes:	Claims	1-25
	No:	Claims	-

2. Citations and explanations

see separate sheet

Preliminary note:
The newly filed claims 1-25 only amount to editorial changes with no real changes having regard to the subject matter claimed.

The current assessment is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. It the later turns out that is not correct, the document D1 cited in the international search report could become relevant.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1- Reference is made to the following documents:
D1: EP-A-1329230
D2: US-A1-2002051730
D3: US-A1-2002133183
D4: WO-A-9856312
D5: US-A-6096070
D6: WO-A-0243619
D7: WO-A-02074194
D8: WO-A-0187372
D9: EP-A-0701802
D10: US-A-6129705

NOVELTY - Art. 33 (1) and (2) PCT

2- Claims 1-23 lack novelty:

2.1- D2: Drug coated stent useful for the local delivery of drug/drug combinations. The type of coating depends on the type of drug (rapamycin and polymer (outer surface) in combination with heparin (inner surface)). The coating may be uniform or not and continuous or discontinuous.
D2 is novelty destroying for the subject matter of claims 1-23.

2.2- D3: Coated stents. Therapeutic drugs, agents or compounds may be mixed with the biocompatible materials and affixed to at least a portion of the stent (rapamycin and heparin).
D3 is novelty destroying for the subject matter of claims 1-23.

2.3- D4: Coated stents: two or more coating layers of polymeric compositions (inner layer, outer layer). The outer layer may be used as drug delivery system. The inner layer may contain a drug too. The stent can have multiple layers of different polymers with the same or different drugs.
D4 is novelty destroying for the subject matter of claims 6-22.

2.4- D5: Coated stent: two or more layers of different bioactive materials. The same bioactive material will generally not be deposited on the different surfaces of the device within the same layer (i.e. each surface of the device carries different bioactive materials).
D5 is novelty destroying for the subject matter of claims 1-23.

2.5- D6: A portion of an inner surface or an outer surface of a stent is coated with a material containing a polymer and a biologically active material.. Inner and outer portion of the medical device can be coated with different materials. Also, there can be more than one coating on a surface and the entire surface of the stent is not necessarily coated.
D6 is novelty destroying for the subject matter of claims 1-23.

2.6- D7: Medicated stent (S1) with a coating comprising a primer layer (a) comprising a first composition (a1) of at least one polymer, and a drug reservoir layer (b) comprising a second composition (b1) of at least one polymer and active agent(s). One or more drug carrier polymer layers can be applied. Different drugs contained within different layers.

D8: Two coating layers: one with polymer and dexomethasone and the other with rapamycin and polymer.

D9: Stent coated with polymer containing a drug.

D10: Balloon, catheter and coated stent.

INVENTIVE STEP - Art. 33 (1) and (3) PCT

3- No inventive step can be acknowledged for the subject matter of claims 1-23, which

lack novelty.

3.1- The features of claims 24-25 are merely some of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

INDUSTRIAL APPLICABILITY - Art. 33 (1) and (4) PCT

4- Claims 1-25 appear to be industrially applicable.

CLAIMS

1. A stent delivery system comprising:
a catheter;
a balloon operably attached to the catheter; and
a stent disposed on the balloon, the stent having a first region and a second region;
a first coating section, the first coating section disposed on the first region; and
a second coating section, the second coating section disposed on the second region;
wherein the first region and the second region are discrete.

2. The stent delivery system of claim 1 wherein the first coating section comprises a first polymer and the second coating section comprises a second polymer.

3. The stent delivery system of claim 2 wherein the first coating section includes a first therapeutic agent and the second coating section includes a second therapeutic agent.

4. The stent delivery system of claim 1 wherein the first coating section includes a therapeutic agent.

5. The stent delivery system of claim 1 wherein the first region and the second region form a pattern selected from the group consisting of ring patterns, striped patterns, spotted patterns, and dot matrix patterns.

6. A coated stent comprising:
a stent, the stent having a first region and a second region;
a first coating section, the first coating section disposed on the first region; and
a second coating section, the second coating section disposed on the second region;
wherein the first region and the second region are discrete.

7. The coated stent of claim 6 wherein the first coating section comprises a first polymer and the second coating section comprises a second polymer.

8. The coated stent of claim 7 wherein the first coating section includes a first therapeutic agent and the second coating section includes a second therapeutic agent

9. The coated stent of claim 6 wherein the first coating section includes a therapeutic agent.

10. The coated stent of claim 6 wherein the first region and the second region form a pattern selected from the group consisting of ring patterns, striped patterns, spotted patterns, and dot matrix patterns.

11. A method for producing a coated stent comprising:

providing a stent, the stent having a first region and a second region;

mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution;

applying the first polymer solution to the first region to form a first coating section;

mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and

applying the second polymer solution to the second region to form a second coating section.

12. The method of claim 11 wherein applying the first polymer solution and applying the second polymer solution further comprises applying the first polymer solution and applying the second polymer solution simultaneously.

13. The method of claim 11 further comprising curing the first polymer solution and curing the second polymer solution.

14. The method of claim 11 wherein applying the first polymer solution to the first region further comprises:

mounting the stent in a coating fixture; and

spraying the first polymer solution on the first region.

15. The method of claim 14 wherein the coating fixture is a computerized numerically controlled machine.

16. The method of claim 14 wherein spraying the first polymer solution on the first region further comprises spraying the first polymer solution by a spraying method selected from the group consisting of micro-spraying and inkjet spraying.

17. The method of claim 11 wherein applying the first polymer solution to the first region further comprises applying the first polymer solution by an application method selected from the group consisting of pad printing, inkjet printing, rolling, painting, spraying, micro-spraying, dipping, wiping, electrostatic deposition, vapor deposition, epitaxial growth, and combinations thereof.

18. A system for producing a coated stent comprising:

means for providing a stent, the stent having a first region and a second region;

means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution;

means for applying the first polymer solution to the first region to form a first coating section; and

means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and

means for applying the second polymer solution to the second region to form a second coating section.

19. The system of claim 18 wherein means for applying the first polymer solution and means for applying the second polymer solution further comprises means for applying the first polymer solution and the second polymer solution simultaneously.

20. The system of claim 18 further comprising means for curing the first polymer solution and means for curing the second polymer solution.

21. The system of claim 18 wherein means for applying the first polymer solution to the first region further comprises:

means for mounting the stent in a coating fixture; and

means for spraying the first polymer solution on the first region.

22. A coated stent comprising:

a stent, the stent having a discrete first region and a discrete second region;

a first polymer including a first therapeutic agent, the first polymer disposed on the discrete first region; and

a second polymer including a second therapeutic agent, the second polymer disposed on the discrete second region.

23. The coated stent of claim 22 wherein the discrete first region and the discrete second region are separated by a bare section.

24. The coated stent of claim 23 wherein the bare section extending between the discrete first region and the discrete second region for a distance of approximately 1 millimeter (0.03937 inches)

25. The coated stent of claim 24 wherein the bare section extending between the discrete first region and the discrete second region for a distance of approximately 0.025 millimeter (0.00098 inches).